

WARNING LETTER

December 5, 1996

Cin 97-124

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

David D'Andrea, M.D.
Mammography Director
Lutheran Medical Center
2609 Franklin Blvd..
Cleveland, OH 44113

Facility I.D.# 121293

Dear Dr. D'Andrea:

Your facility was inspected on November 21, 1996 by a representative from the State of Ohio radiation control program under contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Your records lack the required information that ~~XXXXXXXXXX~~, an interpreting physician is qualified to read mammograms at your facility. Your records did not demonstrate that Dr. ~~XXXXXXXXXX~~ has a state license to practice medicine.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliances that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliances are:

1. There were no records regarding the initial training of 40 hours of continuing medical education in mammography for the interpreting physician: ~~XXXXXXXXXX~~
2. There were no records regarding the initial experience or reading and interpreting mammograms from the examination of at least 240 patients in six (6) months for the interpreting physician: ~~XXXXXXXXXX~~

The other items listed in your November 21, 1996 inspection report identified as Level 3 should also be corrected. We will verify correction of these items during our next inspection and you are not required to address this in your written response.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
and
- sample records that demonstrate proper record keeping procedures, if the noncompliances that were found relate to quality control or other records (**Note: Patient names or identification should be deleted from any copies submitted**).

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

R. Terry Bolen
MQSA Radiological Health Officer
Food and Drug Administration
1141 Central Parkway
Cincinnati, OH 45202.

Also, send a copy to the State radiation control office:

Ms. Terri M. Folmsbee
Ohio Department of Health
Oliver R. Ocasek
Government Office Building
161 S. High St., Suite 400
Akron, OH 44308-1616

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Terry Bolen at (513)684-3501, extension 138.

Sincerely yours,


John R. Marzilli
District Director
Cincinnati District Office

c.
OH/TMFolmsbee